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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/827,495	04/06/01	DELGADO-HERRERA L	6688.US.01

HM22/0814

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EXAMINER	
HUI, S	
ART UNIT	**PAPER NUMBER**
1617	5

DATE MAILED: 08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/827,495	DELGADO-HERRERA ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the vitamin D compounds disclosed in the specification page 3, line 11-page 4, line 5, does not reasonably provide enablement for other vitamin D compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant case, there is no adequate direction provided by the applicant as to how to select any other suitable vitamin D compounds to be used in the invention to treat ICU-associated hypocalcemia. Furthermore, the instant specification does not provide any working examples to show how any other vitamin D compounds may be used successfully in the invention to treat ICU-associated hypocalcemia.

Moreover, it is known in the art that different compounds may have different potency and activity because of the structural and conformational differences in the compounds. Therefore a different vitamin D compounds other than the vitamin D compounds that are disclosed in specification page 3, line 11 - page 4, line 5, may be reasonably expected to yield a different result in treating ICU-associated hypocalcemia. For the same reason, different vitamin D compounds other than the vitamin D

compounds that are disclosed in specification page 3, line 11 - page 4, line 5, may be reasonably expected to yield a different result in treating ICU-associated hypocalcemia. Due to this unpredictability, it would prevent the skilled artisan from determining compounds which may be termed an "vitamin D compound" to retain the desired function of the instant invention to treat ICU-associated hypocalcemia without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "Formula I" renders the claim indefinite because it is unclear what vitamin D compounds is encompassed by the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knutson et al. (US Patent 5,869,473) and Zemplar monograph (Physicians' Desk Reference, April, 1998, page 478-480).

Knutson et al. teaches 1,25-dihydroxy vitamin D_3 is useful in a method of increasing serum calcium level and suppressing the parathyroid hormone (PTH) level at a dosage of at least 0.5μg (See particularly col. 3, line 2-24).

Zemplar monograph teaches that 1,25-dihydroxy-19-nor ergocalciferol is useful in a method of increasing serum calcium level and suppressing PTH level (See particularly page 479, col. 1, Clinical Studies Section, and the second table in col. 2 and 3). Zemplar monograph alsoteaches that the dosage of 1,25-dihydroxy-19-nor ergocalciferol to be 2.8-7μg (See particularly page 480, col.1, Dosage and Administration Section).

The references do not expressly teach the length of therapy to be 1-4 weeks. The references do not expressly teach the vitamin D compounds to be administered daily. The references do not expressly teach the vitamin D compounds to be combined with a pharmaceutically acceptable carrier prior to the administration.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to employ 1,25-dihydroxy vitamin D_3 or 1,25-dihydroxy-19-nor ergocalciferol daily in a method to treat ICU-associated hypocalcemia for 1-4 weeks.

One of ordinary skill in the art would have been motivated to employ 1,25-dihydroxy vitamin D_3 or 1,25-dihydroxy-19-nor ergocalciferol daily in a method to treat ICU-associated hypocalcemia for 1-4 weeks because 1,25-dihydroxy vitamin D_3 or 1,25-dihydroxy-19-nor ergocalciferol are known in the art to be useful in a method to treat the symptoms of ICU-associated hypocalcemia (i.e., hypocalcemia and an increased level of PTH). In addition, the optimization of result effect parameters (e.g., dosing

frequency, dosing regimens) is obvious as being within the skill of the artisan. Furthermore, simply combining the active drugs with a pharmaceutical acceptable carrier (e.g., saline) prior to the administration is within the purview of a skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Minna Moezie

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

San-ming Hui
August 10, 2001